FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)
Gastrointestinal Drugs Advisory Committee (GIDAC)
Hilton Washington DC/North, Gaithersburg, MD
November 5, 2010

Draft AGENDA

To discuss results from clinical trials of proton pump inhibitors in gastroespohageal reflux disease (GERD) in patients less than one year of age, performed in response to a Pediatric Written Request under the Best Pharmaceuticals for Children Act (Nexium, esomeprazole by AstraZeneca LP; Prevacid, lansoprazole by Takeda Pharmaceuticals North America, Inc; Protonix, pantoprazole by Pfizer, Inc.) and Pediatric Research Equity Act (PREA) commitment (Prilosec, omeprazole by AstraZeneca LP). The pathophysiology (disease process) of GERD, its diagnosis and management, and issues related to the design of clinical trials in this age group will be considered.

8:00a.m. – 8:10a.m.	Call to Order Introduction of Committee	Jean-Pierre Raufman, M.D. Chair, GIDAC
8:10a.m. – 8:15a.m.	Conflict of Interest Statement	Kristine Khuc, Pharm.D. Designated Federal Official, GIDAC
8:15a.m. – 8:35a.m.	FDA Opening Remarks	Donna Griebel, M.D. Director, Division of Gastroenterology Products (DGP) CDER, FDA
	FDA Presentation	
	Regulatory Background	Ali Niak, M.D. Medical Officer, DGP, CDER, FDA
8:35a.m. – 10:30a.m.	**GERD in Infants: Honorary Speakers and Presentations**	
	Pathophysiology Diagnosis I-GERQ Survey Instrument	Susan R. Orenstein, M.D. (Speaker) Pediatric Gastroenterology Professor Emerita, Pediatrics University of Pittsburgh School of Medicine Pittsburgh, PA
	Diagnosis and Management	Colin D. Rudolph, M.D., Ph.D. (Speaker and Discussant) Division Chief Pediatric Gastroenterology and Nutrition Children's Hospital of Wisconsin & Medical College of Wisconsin Wauwatosa, WI
	Safety	Eric Hassall, MBChB, FRCPC, FACG (Speaker) Professor of Pediatrics Division of Gastroenterology BC Children's Hospital & University of British Columbia (BC) Vancouver, BC, Canada

AGENDA, cont.

	Clinical Pharmacology	Gregory L. Kearns, PharmD, Ph.D. (Speaker and Discussant) Professor of Pharmacology University of Missouri Kansas City, MO

10:30a.m. – 10:50a.m. Questions to Presenters

10:50a.m. – 11:05a.m. BREAK

11:05a.m. –11:50a.m. **Presentations of Trials by Sponsors: Lessons Learned**

11:05a.m. – 11:20a.m. Takeda (lansoprazole)

11:20a.m. – 11:35a.m. Pfizer (pantoprazole)

11:35a.m. – 11:50a.m. AstraZeneca (esomeprazole)

FDA Presentation

11:50a.m. – 12:00p.m.	Comparative Summary of Trials	John Troiani, M.D., Ph.D. Medical Officer, GDP, CDER, FDA

12:00p.m. – 12:30p.m. Questions to Sponsors and FDA about trials

12:30p.m. – 1:30p.m. LUNCH

1:30p.m. – 2:30p.m. Open Public Hearing

2:30p.m. – 3:30p.m. Committee Discussion and Questions to Committee

3:30p.m. - 3:45p.m. BREAK

3:45p.m. – 5:00p.m. Continued Committee Discussion and Questions to Committee

5:00 p.m. ADJOURN